REMARKS: CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

Claims 1-10, 12, and 13 stand rejected under 35 U.S.C. §103(a) ("Section 103(a)") as obvious over U.S. Patent No. 6,436449 (issued Aug. 20, 2002) ("Gidlund"). Applicant respectfully submits that Gidlund fails to teach the claim limitations recited in the present application because 1) Gidlund teaches the use of extracts not juice; and 2) Gidlund teaches methods for treating tinnitus and suggests that the intake of noni juice might favorably influence pain not methods for treating pain through selective COX-2 inhibition. M.P.E.P. § 2142.

1. Gidlund Teaches the Use of Extracts Not Juice

The independent claims of the present invention have been amended to include "juice" as a limitation. Because Gidlund teaches the use of extracts not juice, Gidlund fails to teach every claimed limitation of the present invention. Gidlund teaches use of an extract derived from the fruits, leaves, the bark or the roots of *Morinda citrifolia* for the manufacture of a medicament for the treatment of a mammal suffering from tinnitus. The present invention claims a method of administering juice to reduce pain through selective COX-2 inhibition. The administration of an extract is different from the administration of juice. Isolating an extract from the fruit and ingesting it to ameliorate tinnitus, as taught in Gidlund, would not produce the desired effect of the claim method of the present application.

The fruit of the *Morinda citrifolia* plant is comprised of several different ingredients. For example the fruit of *Morinda citrifolia* is comprised of: acetic acid, asperuloside, butanoic acid, benzoic acid, benzyl alcohol, 1-butanol, caprylic acid, decanoic acid, (E)-6-dodeceno-gamma-lactone, (Z,Z,Z)-8,11,14-eicosatrienoic acid, elaidic acid, ethyl decanoate, ethyl hexanoate, ethyl octanoate, ethyl palmitate, (Z)-6-(ethylthiomethyl) benzene, eugenol, glucose, heptanoic acid, 2-heptanone, hexanal, hexanamide, hexanedioic acid, hexanoic acid (hexoic acid), 1-hexanol, 3-

hydroxy-2-butanone, lauric acid, limonene, linoleic acid, 2-methylbutanoic acid, 3-methyl-2-buten-1-ol, 3-methyl-3-buten-1-ol, methyl decanoate, methyl elaidate, methyl hexanoate, methyl 3-methylthio-propanoate, methyl octanoate, methyl oleate, methyl palmitate, 2-methylpropanoic acid, 3-methylthiopropanoic acid, myristic acid, nonanoic acid, octanoic acid (octoic acid), oleic acid, palmitic acid, potassium, scopoletin, undecanoic acid, (Z,Z)-2,5-undecadien-1-ol, and vomifol.

The administration of an extract is different from the administration of juice. Gidlund teaches administering extracts derived from *Morinda citrifolia*. Because Gidlund describes a method of administering extracts instead of administering juice Gidlund teaches the administration of a product different from the product claimed in the present invention. Because Gidlund teaches the administration of a different product Gidlund does not render the present invention obvious. Extraction is the process of selecting for and isolating certain ingredients present in the whole. Administering selected ingredients instead of other non-selected ingredients from the list above would produce different biological repercussions. For example, administering potassium instead of myristic acid would result in different biological repercussions. Further, administering whole *Morinda citrifolia* fruit instead of potassium only would result in different biological repercussions.

2. Gidlund Does Not Teach a Method for Reducing Pain By Selective COX-2 Inhibition

Gidlund does not teach selective COX-2 inhibition. Rather, Gidlund teaches administration of extracts for treating tinnitus. Tinnitus is the perception of sound when no external sound is present. Methods of treating tinnitus do not read on methods for reducing pain by selective COX-2 inhibition. Gidlund does suggest that "intake of 100ml of noni juice half an hour before breakfast...might ...favourably influence...pain." Gidlund, Col. 2 lns 3-19.

CONCLUSION

Because the cited prior art fails to teach or suggest all claim limitations of the present invention, Applicants submit that the present invention is not obvious. M.P.E.P. § 2143. Applicants submit that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,

Michael F. Krieger
Attorney for Applicant
Registration No. 35,232

KIRTON & McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111
Telephone: (801) 321-4814
Facsimile: (801) 321-4893

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However, Gidlund does not teach selective COX-2 inhibition. Further, Gidlund does not suggest that the dosage of extract administered to treat tinnitus is an appropriate dosage to "favourably influence...pain."

The difference between treatment of pain and selective COX-2 inhibition is patentable. Compounds or formulations, which favorably influencing pain do not have a reasonable probability for reducing pain by selective COX-2 inhibition. For example, a popular treatment of chronic pain and inflammation involves the use of non-steroidal anti-inflammatory drugs (NSAIDs). While NSAIDs have been effective in reducing inflammation and pain NSAIDs have a number of adverse side effects. The major side effects of NSAIDs are gastrointestinal related. In order to provide relief pain associated with COX-2 without inhibiting COX-1, drug companies have attempted to produce selective COX-2 inhibitors.

Applicants claim "varying the concentration" of doses of *Morinda citrifolia* based on several factors in order to limit undesired COX-1 inhibition relative to COX-2 inhibition. *See Claims 1 and 12.* Applicants' disclosure demonstrates the importance of administering the appropriate concentration of *Morinda citrifolia.* Their experiments demonstrate that at some concentrations, selective COX-2 inhibition was achieved, and at other concentrations it was not. Specification, pg. 15. The Applicants indicated, "the data suggests the surprising result that in some circumstances 'less' *Morinda citrifolia* juice provides 'more' inhibition selectivity." Specification, pg. 15. Applicants' disclosure shows that COX-2 selectivity is undermined by excessive, increased concentrations. Specification, pg. 15. It is only after the inherent COX-1 inhibiting qualities of *Morinda citrifolia* are limited by the methods of the present invention that selective COX-2 inhibition occurs.